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In the Supreme Court of the United States

OCTOBER TERM, 1949

No. 458

COLUSA REMEDY COMPANY, INTERVENER, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The finding of facts and conclusions of law of the United States District Court for the Northern District of Iowa (R. 9) are reported at 78 F. Supp. 721. The opinion of the United States Court of Appeals for the Eighth Circuit (C. R. 5) [1] is reported at 176 F. 2d 554.

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[1] The printed transcript of the record consists of three parts with respect to pagination, i.e. (1) the record filed by appellant in the court below, (2) the supplemental record filed by the appellee in the court below, and (3) the proceedings in the court below. The first part will be designated "R.", the second "S.R.", and the third "C.R."

JURISDICTION

The judgment of the Court of Appeals was entered on July 28, 1949 (C. R. 19). On October 20, 1949, the time for filing a petition for a writ of certiorari herein was extended by Mr. Justice Clark to and including November 18, 1949. The petition for a writ of certiorari was filed on November 17, 1949. The jurisdiction of this Court is invoked under 28 U.S.C. 1254 (1).

QUESTIONS PRESENTED

1. Whether this case is now moot, the drugs involved having been destroyed by the respective United States Marshals.

2. Whether the holding of the district court that the drugs involved were misbranded was justified by the evidence.

STATUTE INVOLVED

The pertinent parts of the Federal Food, Drug, and Cosmetic Act of June 25, 1938 (52 Stat. 1040, 1042, 21 U.S.C. 301, *et seq.*) read as follows:

> Sec. 301. The following acts and the causing thereof are hereby prohibited:
>
> (a) The introduction or delivery for introduction into interstate commerce of any * * * drug * * * that is adulterated or misbranded. [21 U.S.C. 331.]
>
> Sec. 304 (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce, * * * shall be liable to be pro-

ceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: * * * [21 U.S.C. 334.]

STATEMENT

This case arises out of libel proceedings which were instituted by the United States under Section 304(a) of the Federal Food, Drug, and Cosmetic Act, *supra,* in the United States District Courts for the Northern District of Iowa, the District of Colorado, and the Eastern District of Wisconsin for the seizure and condemnation of quantities of articles of drugs labeled in part "Colusa Natural Oil" and "Colusa Natural Oil Capsules" (R. 2-4, 7). Petitioner intervened as claimant (R. 4-5), and inasmuch as the charges contained in the several libels of information were substantially the same, the proceedings which had been instituted in Colorado and Wisconsin were, by stipulation of the parties and orders entered pursuant thereto under Section 304 (b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334 (b)), transferred to the District Court for the Northern District of Iowa and consolidated for trial in that court (R. 7). At the trial of the case it was stipulated that petitioner had shipped the drugs involved in interstate commerce as alleged in the libels of information; that "Colusa Natural Oil" is a natural un-

refined petroleum; and that "Colusa Natural Oil Capsules" contains the same natural unrefined petroleum (R. 20-21). It was further stipulated that the label on the oil stated that that drug was "intended for use in treatment of Psoriasis, Eczema, Athlete's Foot and Leg Ulcers" (R. 21) and that the label on the capsules stated that they were "intended for internal use in treatment of Psoriasis, Eczema, Leg Ulcers" (R. 22). The labels on both the oil and the capsules indicated that the treatments should be continued "until skin is smooth and comfortable" (R. 21, 22). In addition to other evidence, the Government introduced the testimony of three qualified medical experts, who had treated with the oil and capsules several patients who were afflicted with the diseases specified in the labels. Basing their conclusions on that experience, they all testified that in their opinions neither the oil nor the capsules were an effective treatment for the diseases specified (Dr. Rostenberg, R. 35-43, S.R. 2-43; Dr. Trunnell, R. 48-52, S.R. 43-46; Dr. Carney, R. 52-59).

Petitioner introduced the testimony of several physicians and a number of lay witnesses, all of whom stated they had employed the oil and capsules as treatment for the diseases specified in the labels, and that the results were successful (R. 64-124, 135-146).

After trial the district court found that there was no credible or adequate scientific or medical foun-

dation for any claim or representation that "Colusa Natural Oil" or "Colusa Natural Oil Capsules" will cure the diseases specified in the labels placed on those drug articles, and that the said labelling was false and misleading (R. 13-14). The district court thereupon entered a decree directing that the quantities of the drugs seized in each of the consolidated cases be condemned as misbranded and be forfeited to the United States, and "that in each case the United States Marshal shall destroy such of the seized bottles of Colusa Natural Oil and Colusa Natural Oil Capsules which are in the control and custody of said Marshal" (R. 15-16).

On appeal the judgment was affirmed by the court below (C.R. 5-19). The mandate of the court below having issued, and no stay of execution having been sought, on August 29, August 31, September 1, and September 6, 1949, the quantities of drugs involved were, pursuant to the judgment of the district court and the mandate of the court below, destroyed by the marshals of the respective districts.[2]

ARGUMENT

1. These were *in rem* proceedings against the drug articles themselves. See *Hipolite Egg Co.* v. *United States,* 220 U. S. 45, 57. Since the decree of condemnation of the District Court provided for the destruction of the articles, and inasmuch as the decree has been executed by the destruction of the

[2] Certified copies of the Marshals' returns have been lodged with the Clerk of this Court.

said articles, the proceedings are at an end. The identical situation was involved in *United States v. 3 Unlabeled 25-Pound Bags Dried Mushrooms*, 157 F. 2d 722 (C.A. 7), where condemnation proceedings under the Federal Food, Drug, and Cosmetic Act had been instituted against mushrooms alleged to be adulterated. After trial, a decree of condemnation was entered. An appeal was taken to the Court of Appeals, but since no stay of the decree had been obtained by the claimant of the product, the Marshal destroyed it. In dismissing the appeal as moot, the Court of Appeals, per Minton, J., said:

> The continued existence of the mushrooms is essential to our right to proceed against the things themselves. The action is an action in rem. In such a proceeding, there is no party defendant. The goods stand to answer. They are the offenders. Day v. Micou, 85 U.S. 156, 162, 21 L. Ed. 860; National Bond & Investment Co. v. Gibson, D. C., 6 F. 2d 288, 290.
>
> The decree of the District Court goes against the mushrooms. The decree having been entered and executed, the proceeding is functus officio.
>
> Counsel for the Government readily admits the matter is moot here and counsel for the claimant reluctantly admits it is moot, but both parties ask us to decide the issue between them. This we decline to do. If we were to affirm the judgment, the District Court could not destroy the mushrooms. They have already been destroyed. If we reversed the judgment, there

> would be no mushrooms to restore to the claimant. The cause is clearly moot. We are not authorized to decide arguments but only "cases and controversies".

See also *Eureka Productions, Inc.* v. *Mulligan,* 108 F. 2d 760, 761 (C.A. 2), which arose under the customs laws.

It is clear, therefore, since the subject matter of this litigation has been destroyed, that the case is moot and no case or controversy exists under Article 3, Section 2, of the Constitution. See *United States* v. *Hamburg-Amerikanische Packetfahrt-Actien Gesellschaft,* 239 U.S. 466, 475-476; *St. Pierre* v. *United States,* 319 U.S. 41. Cf. *Fiswick* v. *United States,* 329 U.S. 211, 220-223. We submit that for this reason alone the petition for a writ of certiorari should be denied.

2. This case is a sequel to the injunction proceeding involved in *Chester Walker Colgrove and Colusa Remedy Co.* v. *United States,* No. 457 at this Term. The injunction in that case had the effect of requiring the Colusa Remedy Company to provide adequate directions for use in the labeling of the drugs "Colusa Natural Oil" and "Colusa Natural Oil Capsules." See *United States* v. *Colgrove, et al.,* 83 F. Supp. 880 (S. D. Cal.). To do this, the Company included in its labeling representations that the drugs were "intended for use in treatment of Psoriasis, Eczema, Athlete's

Foot and Leg Ulcers" and that the treatment should be continued "until skin is smooth and comfortable" (R. 21). Thereafter, the seizure actions involved here were instituted on allegations that the drugs were falsely represented as an effective treatment for psoriasis, eczema, athletes foot, and leg ulcers (R. 2-4).

Petitioner attacks the finding of the District Court that the labeling of the drugs was false and misleading, as alleged in the libels, on two grounds: first, because this finding was based solely on opinion evidence of medical experts; and second, because the court made this finding notwithstanding testimony of lay witnesses who had used the drug and testified that it was efficacious.

(a) The first ground of attack distorts the evidence presented through the Government medical witnesses. Each of these three witnesses was shown to be outstandingly qualified in the field of dermatology (Dr. Rostenberg, R. 36; Dr. Trunnell, R. 48; Dr. Carney, R. 52). Dr. Rostenberg, an Associate Professor of Dermatology and Assistant Director of the Allergy Unit of the University of Illinois College of Medicine (R. 36), testified concerning the causes, diagnosis, treatment, and prognosis of each of the diseases for which the drug was recommended. Based on his knowledge, training, and experience in the field of dermatology, he testified that the drug would not be an

effective treatment in the diseases for which it is recommended. (S. R. 7, 11, 17, 21.)

Dr. Rostenberg also treated five patients with this drug (S. R. 22) and on the basis of the inefficacy of the drug in the treatment of these patients, evaluated in the light of his knowledge, training, and experience in the field of dermatology, he testified that the drug was worthless in the treatment of the diseases for which it was recommended (S. R. 32-33). It is obvious that Dr. Rostenberg's opinions were based not alone on his general knowledge but also on ineffective results from the use of the drug on patients. Dr. Trunnell used this drug in treating seven patients (R. 48) and Dr. Carney treated six patients who were hospitalized at the University of Iowa Hospital (R. 53-56). Each of these patients was suffering from one of the diseases for which the drug was recommended. The testimony of these two doctors to the effect that the drug was not an efficacious or appropriate treatment for the conditions for which it was recommended was based on actual tests, the results of which they appraised in the light of their professional experience. (R. 56-57; S. R. 43.)

To say, as petitioner does, that the findings of the District Court were based solely on opinion evidence without evidence of observed results in the use of the drug is a misstatement of the facts.

Even if the medical witnesses called by the Government had never used the drug in actual tests their testimony as to its inefficacy would have

been sufficient to support the findings of the District Court. Fraud is not an element of statutory misbranding. An article of drug is misbranded if its labeling is false or misleading in any particular. Section 502(a), 21 U.S.C. 352(a). This is proved by showing that an incorrect statement was made. *United States* v. *One Device, Etc.*, 160 F. 2d 194, 200 (C.A. 10). This Court recently, in *Reilly* v. *Pinkus*, decided November 14, 1949, No. 31, at this Term, considered the scope of the holding in *American School of Magnetic Healing* v. *McAnnulty*, 187 U.S. 94, upon which petitioner relies. The following excerpt from the *Pinkus* opinion refutes petitioner's contention as to the sufficiency of expert medical opinion to support a finding of misbranding (slip opinion, p. 4):

> The contention seems to be that even the testimony of the most experienced medical experts can never rise above a mere "opinion" unless the expert has made actual tests of the drug to determine its effects in relation to the particular representations alleged to be false. The *McAnnulty* holding did not go so far. *We do not understand or accept it as prescribing an inexorable rule that automatically bars reliance of the fact-finding tribunal upon informed medical judgment every time medical witnesses can be produced who blindly adhere to a curative technique thoroughly discredited by reliable scientific experiences* [italics supplied].

It is settled by many Court of Appeals' decisions that a qualified physician may give his opinion as

to the efficacy or lack of efficacy of curative agents, regardless of whether he has had actual experience with the particular article, and that such testimony constitutes sufficient evidence to support a finding concerning the efficacy of the article.[3]

(b) Lay users called by petitioner at the trial testified that they had used the drug for the treatment of skin conditions and that it relieved the conditions, and in some cases they believed their ailment was cured. Petitioner seems to argue that the testimony of these fourteen laymen required a finding that the drug was efficacious in the disease conditions for which it was recommended. This position is untenable.

The satisfied lay users were not permitted to diagnose their conditions or give hearsay testimony as to what doctors had told them with respect to their diseases. They were permitted to describe their symptoms and sufferings. The District Court admitted this testimony and recognized that the question of the weight of such testimony was a matter for its determination. (R. 63.)

In weighing the testimony of these lay witnesses, the District Court might have considered that "the proneness of lay patients to err in accrediting responsibility for benefits to health is well under-

---

[3] *Research Laboratories* v. *United States*, 167 F. 2d 410, 416 (C.A. 9). certiorari denied, 335 U.S. 843; *United States* v. *One Device, etc.*, 160 F. 2d 194, 199 (C.A. 10); *Irwin* v. *Federal Trade Commission*, 143 F. 2d 316, 324 (C.A. 8); *John J. Fulton Co.* v. *Federal Trade Commission*, 130 F. 2d 85, 86 (C.A. 9), certiorari denied, 317 U.S. 679; *Charles of the Ritz Distributors Corp.* v. *Federal Trade Commission*, 143

stood." *Federal Trade Commission* v. *Kay*, 35 F. 2d 160, 162 (C.A. 7). The District Court might also well have been of the view expressed in *United States* v. *50¾ Dozen Bottles* * * * *Sulfa-Seb*, 54 F. Supp. 759, 762 (W. D. Mo.):

> The nature of the simplest disease is so obscure to a layman that his conclusions touching what will benefit it and what will not benefit it mean little.

The District Court made clear its view that in a case of this type testimony from qualified experts is the more satisfactory type of evidence (R. 63).

We submit that the Court of Appeals correctly ruled that "the question whether the labeling on a drug is 'false and misleading in any particular' is a question of fact, and the test to be applied is whether the drug is effective in curing, or giving relief from, the disease for which it is recommended" (C. R. 18). See also, *United States* v. *Six Dozen Bottles* * * * *Dr. Peter's Kuriko*, 158 F. 2d 667 (C.A. 7); *United States* v. *Kaadt*, 171 F. 2d 600 (C.A. 7). On this point the evidence was conflicting. As has been shown there was substantial credible evidence to support the findings of the District Court and it cannot be said that its findings were clearly erroneous.

F. 2d 676, 678 (C.A. 2); *Neff* v. *Federal Trade Commission*, 117 F. 2d 495, 497 (C.A. 4); *Dr. W. B. Caldwell Inc.* v. *Federal Trade Commission*, 111 F. 2d 889, 891 (C.A. 7); *Goodwin* v. *United States*, 2 F. 2d 200, 201 (C.A. 6).

3. Petitioner also contends that Findings 17 and 18 (R. 13) with respect to the meaning of the labeling were unjustified. The labels on which these findings were based are set out in Findings 6 and 7 (R. 10).

This Court said in *United States* v. *Ninety-Five Barrels * * * Vinegar,* 265 U. S. 438, 442:

> It is not difficult to choose statements, designs and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the act.

The meaning of labeling is a question of fact. *United States* v. *7 Jugs * * * Rakos,* 53 F. Supp. 746, 759-760 (D. Minn.), and cases cited. Labeling must be considered in its entirety and the language used is to be given the meaning ordinarily conveyed by it to those to whom it is addressed. *Aronberg* v. *Federal Trade Commission,* 132 F. 2d 165, 167 (C.A. 7); *Hall* v. *United States,* 267 Fed. 795, 797 (C.A. 5).

Petitioner concedes that the label represented that the product would alleviate or relieve in the treatment of the diseases named on the label (S. R. 46). Since the drug was not offered for palliative relief only, and since there was no exception of any ailment embraced within the classes named, it was proper for the District Court to find that the representations were made with respect to the named diseases "of all types and kinds at all stages thereof" (R. 13) *Hall* v. *United States,* 267 Fed.

795 (C.A. 5.) The court might well have found that the statement, "Continue treatment until skin is smooth and comfortable," taken with the rest of the label, represented that continued use of the oil would effect a cure.

This Court said in *Federal Trade Commission* v. *Standard Education Society,* 302 U. S. 112, 116:

> The fact that a false statement may be obviously false to those who are trained and experienced does not change its character, nor take away its power to deceive others less experienced. There is no duty resting upon a citizen to suspect the honesty of those with whom he transacts business. Laws are made to protect the trusting as well as the suspicious. * * *

We submit that the findings of the District Court as to the meaning of the labeling were warranted and that there was no error in the ruling of the Court of Appeals in upholding these findings.

4. There is no merit in petitioner's claim that the courts below applied an erroneous rule as to the degree of proof required. It is the Government's position that in a seizure action under the Federal Food, Drug, and Cosmetic Act it is required to prove its case by a preponderance of the evidence. We believe that *C.C. Co.* v. *United States,* 147 F. 2d 820, 824 (C.A. 5), with its detailed rationale and citation of authorities expresses the correct view as to the degree of proof in such ac-

tions. Accord: *United States* v. *One Device, etc.*, 160 F. 2d 194, 199-200 (C.A. 10). It is true that in *Van Camp Sea Food Co.* v. *United States*, 82 F. 2d 365 (C.A. 3), a case decided under the Food and Drug Act of 1906, 34 Stat. 768 *et seq.*, it was held that the Government had the burden of proving by clear and satisfactory evidence that a product was adulterated. The *C.C. Co.* case points out that that idea was based upon the premise that the earlier Act should be strictly construed because it provided for forfeiture of property. This Court, however, in *United States* v. *Dotterweich*, 320 U. S. 277, has held that the high purposes of the Federal Food, Drug, and Cosmetic Act require that it be given a liberal construction.

So far as the instant case is concerned, it is purely academic to consider what is the proper rule as to the degree of proof required. Neither of the courts below thought that the Government is required to establish its case only by a preponderance of the evidence. The District Court found (Findings 19-20, R. 13-14) that "there is no credible or adequate scientific or medical foundation for any claim or representation that Colusa Natural Oil" will cure, or alleviate, or give relief from, or assist in the treatment of the diseases named on the labels. The court further found that the drug in question "is worthless or without value in the treatment of any or all of said diseases at any stage thereof." These findings of fact will not be set

aside unless clearly erroneous. Rule 52(a), F. R. Civil P. If these findings of fact stand, the conclusion is inevitable, by any standard of proof, that the labeling of the drugs was false and misleading. The Court of Appeals' opinion (C. R. 8-10) carefully and accurately states the applicable law on this point.

CONCLUSION

The drugs involved having been destroyed, the case is now moot. Furthermore, the decision of the court below is correct, and the case warrants no further review. It is respectfully submitted, therefore, that the petition for a writ of certiorari should be denied.

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DECEMBER 1949.

☆ U. S. GOVERNMENT PRINTING OFFICE: 1949 888289 382